REMARKS:

In response to the Office Action mailed November 25, 2008, claim 82 has been amended merely to correct an obvious typographical error. Accordingly, claims 52-55, 66-68, 70-78, 80-83, and 85-107 remain pending with claims 95 and 96 withdrawn from further consideration.

In the Office Action, claims 93, 94, 97, and 100 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,328,753 ("the Zammit reference"). In addition, claims 82-92 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Zammit reference in view of U.S. Patent No. 6,250,307 ("the Conrad et al. reference"), claims 98, 99, and 101 were also rejected under 35 U.S.C. § 103(a) as unpatentable over the Zammit reference in view the Conrad et al. reference, and claims 52-55, 66-68, 70-78, 80, 81, and 102-107 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Zammit reference in view the Conrad et al. reference.

Because neither of the cited references, either alone or in combination, fail to discloses, teaches, or suggests the subject matter of the present claims, the rejections should be withdrawn.

As an initial matter, Applicants appreciate the Examiner's indication that claims 95 and 96 are allowable. However, since claims 95 and 96 were previously restricted and withdrawn from further consideration, Applicants have not rewritten these claims in independent form at this time.

Turning to the Zammit reference, a collapsible nasal-oropharyngeal tube or device 1 is disclosed that is made from a resilient semi-rigid plastic. Col. 2, lines 34-35, col. 3, lines 58-60. The device 1 has a tubular mid-section 4 with flared ends 2, 3 that, when expanded, define a lumen 5 intended to provide an unobstructed airway within a nasal passage. Col. 3, line 66 to col. 4, line 6. At least one end of the device can be coiled, folded, or otherwise collapsed as shown in FIGS. 2 and 3 and held in this collapsed state by a retaining fiber, tie, or clasp. Col. 4, lines 7-13.

When collapsed, the device 1 can be inserted into a patient's nasal passage via the nostril, and then expanded in the nasal passage so as to push against the oropharynx and nasal passage walls to maintain upper airway patency. Col. 3, lines 52-57, col. 4, lines 31-37. Specifically, a retaining tie 6 may be broken allowing the collapsed device 1 to expand as shown in FIG. 7. Col. 4, lines 45-47. In this deployed configuration, the proximal end flange 2 is located at the nostril 9 and the distal end flange 3 should lie at the oropharynx 10. Col. 4, lines 34-36.

Thus, the Zammit device 1 is clearly not deployable in a C-shaped deployed configuration, but is instead introduced in a coiled or folded configuration (see FIGS. 2, 3, 6) that, upon release, resiliently returns to its original tubular shape (see FIG. 7). If the Zammit device 1 remained in its coiled or folded configuration after deployment in a patient's nasal passage, the lumen 5 would be at least partially obstructed, and therefore would not provide an unobstructed airway, as intended.

Turning to the present claims, claim 93 recites an apparatus for treating at least one of sleep apnea and snoring that includes an appliance comprising an elongated loop comprising first and second end portions and two spaced apart elongated elements extending between the first and second end portions, the appliance being sized for introduction into an oropharyngeal region of a human or animal and deployable in a C-shaped deployed configuration in which at least one of the elongated elements extends generally laterally across the posterior wall and the first and second end portions bear against and provide an opening force against the lateral walls of the oropharyngeal region.

First, the Zammit reference does not teach or suggest ***an elongated loop*** comprising first and second end portions and two spaced apart elongated elements extending between the first and second end portions. Instead, the Zammit reference merely discloses a tube that includes flared

ends. These flared ends cannot be properly construed as being end portions of an elongated loop because, if so construed, the two spaced apart elongated members extending between the end portions would be wholly absent. The only structure extending between the flared ends of the Zammit device is the tubular mid-section, which is a singular, unitary tubular structure and does not include two spaced apart elongated members. Applicants can only assume that these are the structures of the Zammit device intended to meet the claim language since the Office Action fails to particularly identify otherwise.

Although one flared end 3 of the tube 1 enters the oropharynx, this flared end cannot properly constitute the recited appliance because the end does not exist other than as part of a tube that extends through the patient's nasal passage. Further, the flared end 3 does not include two laterally positioned elements spaced apart from each other, nor is the flared end 3 deployable in a C-shaped deployed configuration. Instead, the flared end 3 of the Zammit device is intended to open into a circular shape, as clearly shown in FIG. 1.

Second, the Zammit reference fails to disclose, teach, or suggest an appliance deployable in a C-shaped deployed configuration in which at least one of the elongated elements extends generally laterally across the posterior wall and the first and second end portions bear against and provide an opening force against the lateral walls of the oropharyngeal region. As explained above, the Zammit device is not deployable in a C-shaped deployed configuration, and instead expressly teaches against such a deployed configuration since the purpose of the Zammit device is to provide an unobstructed airway.

Third, the Zammit reference does not teach or suggest at least one elongated element that extends generally laterally across the posterior wall of a oropharyngeal region. Instead, the

tubular mid-section 4 of the Zammit device 1 extends through the nasal passage and does not even contact any wall of an oropharyngeal region.

Finally, if the flared ends 2, 3 of the Zammit device 1 could somehow qualify as the recited end portions (which Applicants dispute), these flared ends are incapable of bearing against and providing an opening force against the lateral walls of the oropharyngeal region. In direct contrast, one of the flared ends 2 of the Zammit device 1 is intended to remain within the nostril 9 of a patient being treated, while the other flared end 3 enters the oropharynx.

Accordingly, for these reasons, claim 93 and its dependent claims are neither anticipated by nor otherwise obvious over the Zammit reference.

For similar reasons, claim 100 is also neither anticipated by nor otherwise obvious over the Zammit reference. Similar to claim 93, claim 100 recites an apparatus for treating at least one of sleep apnea and snoring that includes an appliance comprising a single continuous loop comprising first and second rounded end portions and two spaced apart elongated elements extending between the first and second end portions such that the loop defines an open interior space between the spaced apart elongated elements, the appliance being sized for introduction into an oropharyngeal region of a human or animal and deployable in a C-shaped deployed configuration in which the elongated elements extending generally laterally across the posterior wall and the first and second end portions bearing against and providing an opening force against the lateral walls of the oropharyngeal region.

Turning to the Conrad et al. reference, as explained in Applicants' previous response filed February 11, 2008, implants are disclosed for implantation within the soft palate for treating snoring. Col. 2, lines 21-26. In one embodiment, shown in FIGS. 11-16, the implant 20 is a

flexible strip, col. 5, lines 30-41, while in another embodiment, shown in FIGS. 20-23, the implant 30 has an oval shape to cause deformation of the geometry of the soft palate. Col. 7, lines 5-8. Although the implant 30 may be expanded mechanically, the Conrad et al. reference discloses that the implant 30 is preferably formed as a shape-memory alloy that expands to the enlarged (oval) shape in response to the warmth of the body. Col. 7, lines 11-16.

Thus, the Conrad et al. reference fails to disclose, teach, or suggest anything about an appliance comprising an elongated loop comprising first and second end portions and two spaced apart elongated elements extending between the first and second end portions, the appliance sized for introduction into an oropharyngeal region of a human or animal and deployable in a C-shaped deployed configuration, as claimed. Because neither of the cited references teaches or suggests such an appliance, claims 93 and 100 and their dependent claims are not obvious even if the references could be properly combined with one another (which Applicants do not concede).

Turning to the other independent claims, claim 82 recites an apparatus for treating sleep apnea in a human or animal having an oropharyngeal region with lateral and posterior walls, the apparatus that includes an appliance comprising two elongated curved elements made of a biocompatible metal, each of the curved elements having a substantially circular dimension between a first end and a second end extending through more than 90^0 of a circle, the two elements being coupled together at respective first and second ends, and being spaced apart from each other between the first and second ends to define an open interior space therebetween, the appliance being sized and structured to be placed in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of a human or animal with the length of at least one of the elongated elements extending generally laterally across the posterior wall and, when so placed,

being effective in treating sleep apnea, wherein the appliance includes only two elongated curved elements, each of the curved elements has a curved length extending from the first end to the second end, and the first end and the second end define a gap therebetween extending outwardly away from the first and second curved elements having a gap length which is reduced relative to the curved length of each of the curved elements.

First, as explained above, the Zammit reference fails to disclose, teach, or suggest an appliance including two elongated curved elements coupled together at respective first and second ends. More particularly, the Zammit reference does not disclose, teach, or suggest that each of the curved elements has a substantially circular dimension between a first end and a second end extending through more than 90^0 of a circle, the two elements being coupled together at respective first and second ends, and being spaced apart from each other between the first and second ends to define an open interior space therebetween. Instead of two elongated curved elements that are spaced apart from each other and coupled together at their ends, the Zammit reference merely discloses a single, unitary tube that includes a tubular mid-section 4 extending between flared ends 2, 3. None of these structures can be fairly construed as satisfying the recited elongated curved elements.

Further, the Zammit device 1 is not sized and structured to be placed in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of a human or animal with the length of at least one of the elongated elements extending generally laterally across the posterior wall, as claimed. Instead, as explained above, the tubular mid-section 4 of the Zammit device 1 is intended to extend through a nasal passage and not across the lateral and posterior walls of an oropharyngeal region.

Finally, although the Conrad et al. reference discloses using shape memory alloys, this reference also fails to disclose, teach, or suggest an appliance including two elongated curved elements as recited in claim 82, which are also wholly absent from the Zammit reference. Therefore, claim 82 and its dependent claims are also not obvious over the cited references.

Turning to claim 52, a method is recited for treating sleep apnea in a human or an animal having an oropharyngeal region with lateral and posterior walls, a soft palate, a valecullar space and an epiglottis that includes providing an appliance made of a biocompatible metal below a soft palate of a human or animal in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of the human or animal, the appliance so provided having at least two laterally positioned elements substantially longitudinally spaced apart from each other to define an open interior space therebetween and providing an opening force against the lateral walls of the oropharyngeal region.

First, the Zammit reference does not teach or suggest providing an appliance ***below a soft palate*** of a human or animal in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of the human or animal. Instead, the Zammit reference discloses a tube that extends through a nasal passage from a nostril to an oropharynx. Thus, the Zammit device is not provided below the soft palate, but, at most, one end of the Zammit device enters the oropharynx.

Second, the Zammit reference fails to teach or suggest providing an appliance in or radially outwardly from the lateral and posterior walls of an oropharyngeal region, the appliance having at least two laterally positioned elements substantially longitudinally spaced apart from each other to define an open interior space therebetween and providing an opening force against the lateral walls of the oropharyngeal region. As explained above, the Zammit device does not

include two laterally positioned elements spaced apart from each other to define an open space therebetween, but merely includes a single, unitary tube.

Because the Conrad et al. reference also fails to disclose, teach, or suggest such an appliance (see Applicant's response filed February 11, 2008, pages 14-15), claim 52 and its dependent claims are also not obvious over the cited references.

Finally, claim 102 recites a method for treating at least one of sleep apnea and snoring that includes providing an appliance comprising a continuous loop comprising first and second end portions and two spaced apart elongated elements extending between the first and second end portions; introducing the appliance into an oropharyngeal region; and releasing the appliance within the oropharyngeal region such that the elongated elements extends generally laterally across the posterior wall and the first and second end portions bear against and provide an opening force against the lateral walls of the oropharyngeal region.

First, as explained above, the Zammit reference does not teach or suggest an appliance comprising a continuous loop comprising first and second end portions and two spaced apart elongated elements extending between the first and second end portions, as claimed.

Second, the Zammit reference fails to disclose, teach, or suggest anything about releasing an appliance within an oropharyngeal region. Instead, the Zammit reference merely discloses a tube that is deployed within a nasal passage. Although one end of the tube enters the oropharynx, the tube is not intended to nor incapable of being ***released*** within an oropharyngeal region.

Finally, the Zammit reference does not teach or suggest releasing an appliance within the oropharyngeal region such that the elongated elements extends generally laterally across the posterior wall and the first and second end portions bear against and provide an opening force

against the lateral walls of the oropharyngeal region. The Zammit tube does not include any structure that can be fairly characterized as such elongated elements nor end portions that provide an opening force against lateral walls of an oropharyngeal region.

Since the Conrad et al. reference also fails to teach or suggest such an appliance, claim 102 and its dependent claims are not obvious over the cited references.

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Applicants hereby petition for any extension of time necessary to make the present response timely. Applicants believe that a two month extension is currently required.

Respectfully submitted,
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